DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 5, 2014

NeuroInvent Inc.
Chao-Shent Chao
Manager and Contact Window of Taiwan NeuroInvent Inc.
19925 Stevens Creek Blvd.
Suite 100
Cupertino, CA 95014-2358

Re: K142470
Trade/Device Name: E-Shield Multi-paired Subdermal Needle Electrodes
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: September 30, 2014
Received: October 6, 2014

Dear Mr. Chao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: E-Shield Multi-paired Subdermal Needle Electrodes

Indications for Use:

E-Shield Multi-paired Subdermal Needle Electrodes are intended for use with recording and monitoring equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael J. Hoffmann -S
2014.11.05 10:09:39 -05'00'

510(k) Summary

5.1 Type of Submission: Special

5.2 Preparation Date: 22th August, 2014

5.3 Submitter:

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Contact: Chao-Shent Chao
(kuo-tai-hospitals@hotmail.com)

5.4 Identification of the Device:

Trade name: E-Shield Multi-paired Subdermal Needle Electrodes

Classification Name: Needle Electrode

Device Classification: II

Regulation Number: 882.1350

Panel: Neurology

Product Code: GXZ

5.5 Identification of the Predicate Device:

Predicate Device Name: E-Shield Multi-paired Subdermal Needle Electrodes

Manufacturer: NeuroInvent Inc.

Product Code: GXZ

510(k) Number: K140200

5.6 Intended Use

E-Shield Multi-paired Subdermal Needle Electrodes are intended for use with recording and monitoring equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.

5.7 Device Description

E-Shield Multi-paired Subdermal Needle Electrodes are single use, disposable, monopolar, non-pyrogenic and sterilized stainless steel subdermal needle electrodes. Electrodes are applied in the study of biopotentials such as electroencephalograph (EEG), electromyography (EMG). Electrodes are invasive as they are placed subcutaneously or in contact with nerve or muscle tissue.

The subdermal needle electrodes can be used to record variety of types of neurological and neurophysiological evoked potentials, including but not limited to electroencephalogram (EEG), electromyogram (EMG) in hospital and clinical setting. It is highly recommended to be used of intra-operative neuromonitoring (IOM).

The electrodes consist of a stainless steel needle with a lead wire attached and the lead wires terminate in a safety connector. The electrodes are used under the supervision of a physician. There are three specifications for E-Shield Multi-paired Subdermal Needle Electrodes, 7mm, 13mm and 19mm. The sterilized PET box contains 2 sets of 5-paired, 2 sets of 4-paired or 1 set of single subdermal needle electrodes and a safety shield attached to each set. The safety shield is used to cover the needle sharps and the multi-paired lead wires are designed in group for easy organizing. Grouped wire cable can be separated into multi-paired lead wires to reach different recording sites of a patient over desired length. For instance, it can be used for the recording in one limb muscle groups.

5.8 Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the E-Shield Multi-paired Subdermal Needle Electrodes.

Testing Item	Standard and regulations applied
Sterilization	ISO 10993-7: 2008 Biological evaluation of medical device -Part 7: Ethylene Oxide sterilization residuals.
	ISO 11135-1: 2007 Sterilization of health care products - Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices.
	ISO 11135-2: 2008 Sterilization of health care products - Ethylene oxide –Guidance on the application of ISO 11135-1.
	ISO 11737-1: 2006 Sterilization of Medical Devices – Microbiological Method – Part 1: Determination of a population of microorganisms on products.
	ISO 11737-2: 2009 Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
Shelf life	ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Medical Device Packages.
	ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials.
	ASTM F1140-13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications.
	ASTM F1929-12 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.
	ASTM D4332: 2001 Standard practice conditioning containers, packages or packaging components for testing.
	ASTM F1608 Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method).

	ISO 11607-1 Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems. (Sterility)
	ISO 11607-2 Packaging For Terminally Sterilized Medical Devices - Part 2: Validation Requirements For Forming, Sealing And Assembly Processes. (Sterility)
	ASTM D4169-09, Standard Practice For Performance Testing Of Shipping Containers And Systems. (Sterility)
	The International Safe Transit Association (ISTA) Procedure 1A
	ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
Biocompatibility	ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity.
	ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
	ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
	ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference material.
	ASTM F756-08, Standard Practice For Assessment Of Hemolytic Properties Of Materials. (Biocompatibility)
	USP 35-NF30:2012, <151> Pyrogen Test (USP Rabbit Test). (Sterility)
	ASTM F750-87 (Reapproved 2012), Standard Practice For Evaluating Material Extracts By Systemic Injection In The Mouse. (Biocompatibility)
	USP <85>, Bacterial endotoxin test. Chapter 85, USP version 36.
	USP <161>, Transfusion and infusion assembles and similar Medical devices. Chapter 161, USP version 36.
Electromagnetic	IEC 60601-1 Medical electrical equipment Part 1: General

Compatibility & Electrical Safety	requirements for basic safety and essential performance.
Performance	ISO 9626 First Edition 1991-09-01, Amendment 1 2001-06-01 Stainless Steel Needle Tubing For The Manufacture Of Medical Devices. (General Plastic Surgery/General Hospital)
	ASTM B193-87(1992) : Standard Test Method for Resistivity of Electrical Conductor Materials.
	IEC 60028 (1925) : International standard of resistance for copper.
	GB/T 3048.2-2007: TEST method for electrical properties of electric cables and wire-part2: Test of electrical resistivity of metallic materials.

All the test results demonstrate E-Shield Multi-paired Subdermal Needle Electrodes meet the requirements of its pre-defined acceptance criteria and intended uses.

5.9 Clinical Testing

No clinical test data was used to support the decision of safety and effectiveness.

5.10 Substantial Equivalence Determination

E-Shield Multi-paired Subdermal Needle Electrodes has the same intended use, fundamental scientific technology and technological characteristics as the predicate device, E-Shield Multi-paired Subdermal Needle Electrodes (K140200). Information described below can demonstrate the E-Shield Multi-paired Subdermal Needle Electrodes is substantial equivalent to the predicate device.

	Proposed Device	Predicate Device
Item	E-Shield Multi-paired Subdermal Needle Electrodes	E-Shield Multi-paired Subdermal Needle Electrodes (K140200)
Classification	II	II
Regulation No.	882.1350	882.1350

Product Code	GXZ	GXZ
Intended Use	E-Shield Multi-paired Subdermal Needle Electrodes are intended for use with recording and monitoring equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.	E-Shield Multi-paired Subdermal Needle Electrodes are intended for use with recording and monitoring equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephagraph (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only.
Design	Monopolar	Monopolar
Anatomical sites	Subdermal, nerve or muscle tissue	Subdermal, nerve or muscle tissue
Materials	Stainless steel needle with lead wire attached.	Stainless steel needle with lead wire attached.
Sterility	EO	EO
Shelf life	3 years	3 years
Mechanical safety	Packaged needle covered with a needle cover	Packaged needle covered with a needle cover
Specification-Needle Length	7mm, 13mm and 19mm	13mm and 19mm
Specification-category	➢ 2 sets of 4 or 5-paired subdermal needle electrodes for 7mm, 13mm and 19mm ➢ 5, 7 or 9-Single Subdemal Needle Electrodes for 13mm	➢ 2 sets of 5-paired subdermal needle electrodes for 13mm and 19mm

5.11 Similarity and differences

The proposed device is the same in intended use, design, technological characteristics and materials as the predicate device. The only difference between the proposed device and the predicate device is the specification. The proposed device added 7mm - Needle Length as new specification and revised codes of products. The category was modified as well. There are 2 sets of 4 or 5-paired subdermal needle electrodes and 1 set of single Subdemal Needle Electrodes for proposed device. The predicate device only contains 2 sets of 5-paired subdermal needle electrodes.

The proposed device has tested on safety and performance tests and the test results were complied with the test requests. Therefore, the difference of proposed device and predicate device did not raise any problems of safety or effectiveness. The proposed device is substantially equivalent to the predicate device in intended use, design and performance claims.

5.12 Conclusion

After analyzing bench tests and safety testing data, it can be concluded that E-Shield Multi-paired Subdermal Needle Electrodes is as safe and effective as the predicate device.